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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,215	07/30/2001	Jean Francois Michelet	P66893US0	8358

7590 08/13/2003

JACOBSON HOLMAN  
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WASHINGTON, DC 20004

EXAMINER
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YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 08/13/2003 //

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/917,215

Applicant(s)

MICHELET ET AL.

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on April 1, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

Receipt is acknowledged of Amendment file don April 1, 2003. Claims 1-26 are pending. Claim rejections under 35 U.S.C. §§ 102 and 103 are withdrawn in view of applicants' remarks. Claim rejection under 35 U.S.C. § 112, first paragraph is maintained in part and withdrawn in part. New rejections are made in view of further consideration.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1-26 are rejected for lack of written description. While the specification recites using "EP-3 receptor antagonist", there is no disclosure as to what compounds are actually used for the claimed invention. It is noted that specification on p. 4, first full paragraph that applicants teach "the non-prostanoic antagonist L789106" as an example of an EP-3 receptor antagonist. However, while applicants discloses this single example of EP-3 receptor antagonist, there is no teaching in the specification that this is what applicants are actually using in the invention or what the EP-3 receptor

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antagonists are in fact effective for the claimed method. Applicants define in the specification p. 6, last paragraph, the expression "prostaglandin EP-3 receptor antagonist" as "antagonist compounds which make it possible to attenuate, reduce or stop the loss of head hair and other hairs". Examiner views that this definition does not convey to a skilled artisan that applicants in fact had in possession the specific prostaglandin EP-3 receptor antagonist useful for the claimed effect. Examiner notes that the example formulations in the specification merely shows using "prostaglandin EP-3 receptor antagonist", and does not disclose what compounds applicants are actually employing in the formula.

Similarly, while claim 18 recites using prostaglandin EP-2 receptor agonist and prostaglandin EP-4 receptor agonist, applicants do not disclose what actual compounds are used in the invention, or what the scope of the limitation is.

Claims 13-16, 18, and 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' specification and prior art do not enable method of stopping the loss of hair. The specification and prior art do not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim without undue experimentation.

Factors to be considered in determining whether any necessary experimentation is "undue" include, but are not limited to: the breadth of the claims; the nature of the invention; the state of the prior art, the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See In re Wands, 858 F.2d 731, 737, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988).

Applicants' disclosure fails to enable the claimed method of "stopping the loss of hair". The burden of enabling the prevention of a natural condition such as the loss of hair (i.e., the need for additional testing) would be greater than that of enabling a treatment due to the need to screen the subjects for prolonged period of time. In the instant case, the specification does not provide guidance as to how one skilled in the art would go about stopping the loss of hair within the scope of the presently claimed invention. Nor is there any guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed method in stopping the hair loss. Undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed method.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-19 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

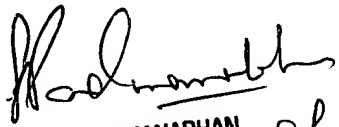
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu  
Patent Examiner  
August 10, 2003

  
SREENI PADMANABHAN  
PRIMARY EXAMINER 8/10/03